UNITED STATES PATENT AND TRADEMARK OFFICE

CIC

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,923	12/19/2001	James Thacker	38599.0015	9929

7590 06/14/2005

James Remenick
Powell Godstein LLP
901 New York Ave, NW
Third Floor
Washington, DC 20001-4413

EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 06/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/020,923	THACKER, JAMES	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-19 and 25-30* is/are pending in the application.

4a) Of the above claim(s) *6-10,12-19 and 25-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,29 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *6-19 and 25-30* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. The amendment filed November 19, 2004 has been entered. The examiner acknowledges the amendment to the specification. Claims 1-5, and 20-24 are cancelled. Claims 6-7 and 11-12 have been amended. Claims 25-30 have been newly added.

Election/Restrictions

2. Amended claims 6-7 and 12 and newly submitted claims 25-28 are directed to inventions that are independent or distinct from the invention originally claimed for the following reasons: The inventions are distinct, each from the other because of the following reasons: The inventions in claims 6,7and 12 are related as distinct methods because they are different methods with different method steps and different functions and those result in different final outcomes. First, the instant specification does not disclose that these methods would be used together, rather the specification states that the methods are separate and distinct. The methods are drawn to detecting different microorganisms. Moreover, the methods are unrelated as they comprise distinct steps and utilize different products which demonstrate that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material. For instance, the method drawn to claim 6 detects actively respiring microorganisms; has a trapping step wherein the trapping is on a solid filtration membrane; and contacts a primary prepared against a substituted formazan and secondary antibody. Such steps are not be necessary to practice the other methods.

In this case, the methods are separate and distinct, since only the method of claim 7 requires the use of a lysozyme to form cellular debris wherein the viability marker is adsorbed on the surface of the cellular debris. Therefore, each method is divergent with respect to the types of microorganisms being detected and their associated steps. For these reasons the inventions of claims 6,7 and 12 are patentably distinct.

Furthermore, searching the inventions of claims 6,7 and 12 would impose a serious search burden. A method of detecting actively respiring microorganisms comprising trapping the microorganism in a solid filtration membrane requires a different search than the other methods. Thus, a search drawn to this method is not necessary for a determination of novelty and unobviousness of the method of claim 7 which does not comprises those steps. Furthermore, the method of claim 6 may be known even if the method of claim 7 is novel. In addition, the technical literature search for the method of claim 12 and the method of claim 11 are not coextensive, since the method of claim 12 may be characterized in the technical literature prior to discovery of the method of claim 11.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 6-10, 12-19 and 25-28 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Claims 11 and 29-30 are under consideration in this application.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on August 23, 2004 was filed after the mailing date of the non-final action on May 5, 2004. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner is considering the information disclosure statement.

Withdrawal of Objections and Rejections

4. The following objections and rejections have been withdrawn in view of applicants' amendments and arguments:

a) The written description rejection of claim 11 under 35 U.S.C. 112, first paragraph drawn to viability marker and reporter molecule; and

b) The rejection of claim 11 under 35 U.S.C. 112, second paragraph.

Response to Arguments

5. Applicant's arguments filed November 19, 2004 have been fully considered but they are not persuasive.

Terminal Disclaimer

6. Claim 11 was provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-25 of copending Application No. 10/053,871. Applicant responded by submitting a Terminal Disclaimer between the instant claims and U.S. Patent 6,344,332. This terminal disclaimer fails to address the provisional rejection and is not proper since the provisional rejection was between the instant claims and the

claims of 10/053,871. Therefore, the provisional double patenting rejection will remain in place since the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. The rejection of claims 11 and 29-30 under 35 U.S.C. 103(a) as being unpatentable over Shih et al., (US Patent 4,026,767 published May 31, 1977) in view of Harlow and Lane (1986) is maintained. The rejection was on the grounds that no more than routine skill would have been required to modify the method of detection as taught by Shih et al., to further incorporate using specific antibodies within the colorimetric assay as taught by Harlow and Lane.

Applicants assert that the amendment to the preamble being drawn to the method being capable of detecting less than 10,000 cfu of microorganisms/ml overcomes the rejection. However, in response to applicant's argument, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). In this case, the method of Shih et al., in view of Harlow and Lane is capable of detecting less than 10,000 cfu of microorganisms/ml and taking less than two hours to perform.

no steps within the instantly claimed method which prevent the prior art method from detecting less than 10,000 cfu of microorganisms/ml. Moreover, applicants' have not presented any evidence to the contrary, stating that the prior art method is not capable of detecting less than 10,000 cfu of microorganisms/ml or taking less than two hours to perform. Therefore, applicants' arguments are not persuasive and the rejection is maintained.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 11 and 29-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claim 11 is drawn to a method for detecting 10,000 cfu/ml or less of microorganisms comprising: incubating the microorganisms with a nutrient medium containing a predetermined amount of a viability substrate, wherein metabolism of said

viability substrate by the microorganisms produces a viability marker; digesting the microorganisms; incubating the digested microorganisms with a primary antibody specific for the viability marker; conjugating the primary antibody to a reporter molecule to form a reporter-primary antibody complex; and detecting the reporter molecule.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.,* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli,* 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood,* 107 F.3d at 1572, 41 USPQ2d at 1966." *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP 2163.

The claims are so broad that they encompass the detection of every type of microorganism, however applicants have not described such a method. The instant specification fails to provide a method wherein all microorganisms are detected with only one primary antibody. The specification fails to teach that every type of microorganism can be used within the claimed method. There is no teaching that incubating the microorganisms with a nutrient medium containing a predetermined amount of a viability substrate, wherein metabolism of said viability substrate by the microorganisms produces a viability marker will produce a marker in all parasites, viruses, fungi, yeasts and bacterium. Moreover, there is no teaching that all forms of microorganisms can be detected with said method.

There is no written description of any method steps which teach such broadly claimed methods. There are no examples that teach the detection of each and every type of microorganism. The claims fail to recite the necessary method steps, such as how the detection of the microorganisms occurs. There are no data showings that the marker will be found in every microorganism. The specification does not provide a substantive description that the claimed method is capable of detecting the marker in all microorganisms. This demonstration is required for the skilled artisan to be able to use the claimed method for their intended purpose of detecting the microorganisms. The generic statements drawn to the method of detecting 10,000 cfu/ml or less of microorganisms does not provide ample written description for the method. Furthermore, the statements the method being capable of detecting viruses, parasites

and fungi does not sufficiently provide ample written description since only bacteria will metabolize the viability substrate and produce a viability marker.

As stated earlier, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable claim 11 is a broad generic with respect all possible microorganisms encompassed by the claims. The possible structural variations are limitless to any class of microorganisms. Moreover, the specification lack sufficient variety of species to reflect this variance in the genus since the specification does not provide any examples of anything other than bacteria. The specification is void of any microorganism which could be used within the instantly claimed method. The specification is limited to bacteria. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. *See In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention and the claims are rejected.

10. Claims 11 and 29-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The preamble of the claims is drawn to a method for detecting 10,000 cfu/ml or less of microorganisms, however the recited steps within the method comprise an incubation step; a digesting step; an incubation step; a conjugation step; and a detection step where the reporter molecule is detected. There is no correlation step which correlates the detection of the reporter molecule to detecting 10,000 cfu/ml or less of microorganisms. Therefore, the goal of the preamble is not commensurate with the steps of the method that are drawn to detecting microorganisms.

Claim 29 is unclear with respect to the microorganisms comprising 1,000 cfu/mL or less what microorganisms' applicant is referring too, i.e., the ones within the first incubation step or the digested microorganisms. Furthermore, it is unclear whether applicant is stating that when the first incubation occurs with 1,000 cfu/mL or less of microorganisms; if so it is unclear how/why one skilled in the art already knowing how many microorganisms are present would perform this method of detection.

11. Claims 11 and 29-30 are rejected as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MEP. § 2172.01. The claims lack an essential correlation step that correlate the detected reporter molecule to detecting microorganisms as previously discussed. Therefore appropriate correction is required.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
June 7, 2005

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600